## REMARKS

### *Status of the Claims*

Claims 15, 21, 28–30, 51–54, and 57-60 were pending in the application.

Claims 15, 21, 28–30, 51–54, and 57-60 were rejected and the rejection was made final.

Applicants request that this amendment be entered in order to amend claims s 15, 21, 28, 51–54 and 57-60.

Upon entry of this amendment, claims 15, 21, 28–30, 51–54, and 57-60 will be pending.

### *Summary of the Amendment*

Applicants request that claims 15 and 28 be amended to correct confusing language in reference to the DmGPCR7 protein. Each claim included a reference to the nucleic acid sequence (SEQ ID NO:17) that encodes DmGPCR7 protein (SEQ ID NO:18). Moreover, the claim language was deemed confusing in the reference to the DmGPCR7 protein in phrase referring to its coding sequence. Correction by the amendment herein does not add new matter or raise any new issues. Correction by the amendment places the claims in better condition for allowance or appeal. Accordingly, entry of the amendment is appropriate.

Applicants request that claim 21 be amended to correctly refer to the claim from which it depends. In the previous amendment, the limitation of claim 20 was fully incorporated into claim 15. The dependency of claim 21, however, was mistakenly not amended. Correction by the amendment herein does not add new matter or raise any new issues. Correction by the amendment places the claims in better condition for allowance or appeal. Accordingly, entry of the amendment is appropriate.

Applicants request that claims 51–54, and 57-60 be amended to make the claim language more clear. In the previous amendment, clams 15 and 28 were amended to specifically refer to the DmGPCR as DmGPCR7. In deleting references to other DmGPCR molecules, the amendments of claims 51-54 and 57-60 included redundant Markush language and/or references to DmGPCR7 which, upon entry of this amendment, will be deleted.

Correction by the amendment herein does not add new matter or raise any new issues. Correction by the amendment places the claims in better condition for allowance or appeal. Accordingly, entry of the amendment is appropriate.

***Claim Rejection under 35 U.S.C. §101***

Claims 15, 28–30, 51–54, and 57-60 stand rejected under 35 U.S.C. §101 because it is alleged that they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. It is asserted in the Official Action at pages 3-4 that the claims lack a specific and substantial utility because it is asserted that

> [t]here is absolutely no evidence provided by the instant specification that a compound that activates or inhibits the activation of a DmGPCR7 protein of the instant invention has insecticidal activity. The text in paragraph 00373 on page 108 of the instant specification demonstrates that a DmGPCR7 protein of the instant invention is activated by leucokinins. The text in paragraph 0012 on page 5 of the specification discloses that "[l]eucokinins are a group of widespread insect hormones that stimulate gut motility and tubule fluid secretion rates", that "[i]n tubules, their major action is to raise chloride permeability by binding to a receptor on the basolateral membrane" and that "[l]eucokinin acts by raising intracellular calcium in only the stellate cells". There is no evidence presented in the specification that leucokinins, or antagonist thereto, are insecticidal.
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> In fact, there is no evidence that the known actions of leucokinins are mediated by a DmGPCR7 of the instant invention. The instant specification discloses a plurality of different DmGPCRs that are activated by leucokinins but fails to disclose the identity of those tissues or organs in which DmGPCR7 is specifically expressed. Therefore, the instant application has failed to establish a nexus between the activation of DmGPCR7 by a leucokinin and a specific physiological response in an insect that would either be required for viability or result in death. The instant application clearly leaves it to the artisan to make the additional contributions needed to discover if the activation, inhibition, or both the activation and inhibition of DmGPCR7 results in insect death.

The case law cited in the Official Action relates to the establishment of a practical utility in the determining the date an invention has been actually reduced to practice in interference matters. While Applicants respectfully urge that the cases cited in the Office Action are not dispositive in the current analysis, Applicants' position is fully consistent with the body of law to which the cited cases belong. Applicants respectfully urge that the more informative case law relative to the instant application is discussed in those sections for the MPEP which refer to utility analyses and rejections in *ex parte* prosecution (for example MPEP 2107 et seq.). Applicants respectfully urge that the Office is misapplying the law and the Office's own guidelines with respect to the instant application.

The Office contends that Applicants have failed to establish a practical utility because there is no data showing a relationship between DmGPCR-mediated activity and insect death. Thus, the Office contends, those skilled in the art could not employ the assay without making substantial inventive contributions. (Official Action at page 5) Applicants respectfully disagree.

It is well established that in order to make a proper utility rejection, the Office must establish a *prima facie* case that the invention lacks a specific and substantial credible utility. Respectfully, the Office has not made such a case in the instant application. The claimed invention has a specific and substantial credible utility under the law. The burden is on the Office to establish a *prima facie* case. The Office has not met its burden.

The specification clearly states that the invention is useful to identify novel agents that can modulate receptor-ligand interactions in insects as a means of identifying compounds that can be used to effect insect populations. GPCRs are a recognized superfamily of receptor proteins which have vital roles in communication between cells and their environment. The specification identifies DmGPCR7, the receptor referred to in the claims, as well as its binding partner, leucokinins, a family of insect hormones known to have specific physiological effects on insects.

The asserted utility is specific and substantial. That is, as required by the law and Office's own guidelines, the asserted utility is useful for particular practical purpose. It is not a "throw-away, insubstantial or non-specific utility." Rather it provides a well-defined and

particular benefit to the public. Additionally, the invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research.

To satisfy the substantial utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public. The invention is a clear benefit to the public and does not require further discoveries to allow the public to put it to use for its asserted utility at this time. There is nothing in the record that establishes that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. A lack of data as discussed in the Official Action does not render the utility non-specific and insubstantial under the law and Office's own guidelines.

Applicants urge that the basis for the utility rejection, that the absence of data showing a relationship between DmGPCR-mediated activity and insect death would require one skilled in the art to make substantial inventive contributions in order to employ the assay is incorrect. The Office suggests that those skilled in the art cannot currently practice the invention without knowing where DmGPCR7 is expressed. This is factually incorrect. Those skilled in the art could identify modulators of DmGPCR7-leucokinin interaction without knowing which organs or tissues express the receptor. Those skilled in the art can practice the invention without knowing where DmGPCR7 is expressed. The Office states that those skilled in the art cannot currently practice the invention without knowing what type of DmGPCR7-leucokinin modulation (activation or inhibition) will result in insect death. There us nothing in the record to support the Examiner's contention that that one skilled in the art would conclude that altering of normal receptor-ligand interactions would not be disruptive to the treated insect. Unlike the chemical intermediates in *Brenner v. Manson* 148 U.S.P.Q. 689 (Sup. Ct. 1966), the claimed invention does not require discovery of another invention before it can be used. The claimed invention is in currently available form.

To properly reject a claimed invention under 35 U.S.C. 101, the Office must make a *prima facie* showing that the claimed invention lacks utility, and provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. The absence of data is not a sufficient evidentiary basis.

The standard for determining whether an asserted utility is not specific or substantial requires a *prima facie* showing to establish that it is **more likely than not** that a person of ordinary skill in the art would not consider any utility asserted by the applicant to be specific and substantial. That is, the Office must establish that one skilled in the art would think there is a better chance that the invention does not have a currently available, well-defined and particular benefit to the public than that it does. The Office provides no evidence in support of the rejection and the reasoning refers exclusively to why one skilled in the art might question the operability of the invention, not why they would conclude it is **more likely that the invention will not work than it is that it will**.

The mere absence of proof of operability does not lead one skilled in the art to conclude an invention is unlikely to work. The record indicates that the superfamily of receptors is known to be involved in vital functions and that the binding partner of the receptor is a physiologically active hormone. These facts are fully consistent with the invention having a specific and substantial utility. The absence of additional facts does not make the one skilled in the art **more likely than not** to conclude that claimed invention lacks a specific and substantial utility. The requirements of the *prima facie* showing have not been met. The Office has speculated the possibility that the claimed invention may not work but such speculations do not establish one skilled in the art would **more likely than not** conclude that the invention lacks a specific and substantial utility.

It is insufficient for one skilled in the art to conclude that the claimed invention may require additional inventions in order to have a utility in currently available form. Rather, to properly support the rejection under 35 U.S.C. §101 the Office has the burden to establish that that one skilled in the art would conclude to that the claimed invention **more likely than not** requires additional inventions in order to have a utility in currently available form. There is no evidence of record to support a finding that one skilled in the art would conclude to that the claimed invention **more likely than not** requires additional inventions in order to have a utility in currently available form. The Office has not met their burden.

Claims 15, 21, 28–30, 51–54, and 57-60 have a specific and substantial credible utility. Applicants respectfully request that the rejection of claims 15, 28–30, 51–54, and 57-60 under 35 U.S.C. §101 be withdrawn.

***Claim Rejections Under 35 U.S.C. § 112, first paragraph***

Claims 15, 28–30, 51–54, and 57-60 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to adequately teach how to use the instant invention. This rejection has been issued in combination with the rejection issued under 35 U.S.C. §101. Applicants traverse the rejection and respectfully request that the rejection be withdrawn.

Applicants note the rejection under 35 U.S.C. 112, first paragraph, set forth in paragraph 9 of the Official Action is based on grounds related to the "lack of utility" under 35 U.S.C. 101. In particular, it is asserted that the "how to use" requirement is not met for the reasons given with regard to the rejection under 35 U.S.C. 101.

As discussed above, the rejection of claims 15, 28–30, 51–54, and 57-60 was improperly issued under 35 U.S.C. § 101 for allegedly not containing specific and substantial credible utility. Applicants respectfully urge that the application is in compliance with the utility requirement and therefore the rejection under both 35 U.S.C. § 101 and 35 U.S.C. 112, first paragraph should be withdrawn. As set forth above, the application has a specific and substantial credible utility. Accordingly, the rejection under 35 U.S.C. 112, first paragraph, as well the rejection under 35 U.S.C. §101 rejection should be withdrawn.

***Claim Rejections Under 35 U.S.C. § 112, first and second paragraph***

Claims 15, 28-30, 51-54 and 57-60 stand rejected under 35 U.S.C § 112, first paragraph as failing to comply with the written description requirement and 35 U.S.C § 112, second paragraph allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the claimed invention.

Claims 15 and 28 have been amended to correct the error in the language and reference to the DmGPCR amino acid sequence. The amendment obviates the basis of rejection.

The application is in compliance with the requirements of the first and second paragraphs of section 112. Applicants respectfully request that the rejections of claims 15, 28-30, 51-54 and 57-60 under 35 U.S.C. § 112, first paragraph, and 35 U.S.C § 112, second paragraph, be withdrawn.

***Claim Rejections Under 35 U.S.C. § 112, second paragraph***

Claims 21, 51-53 and 57-60 stand rejected under 35 U.S.C § 112, second paragraph, allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the claimed invention.

Claim 21 has been deemed vague due to a failure to update its dependency when the limitations of claim 20 were incorporated into claim 15. The amendment obviates the basis of the rejection.

Claims 51-53 and 57-60 have been deemed vague and indefinite because Markush language rendered unnecessary was not deleted in the earlier amendment. The amendment obviates the basis of the rejection.

The application is in compliance with the requirements of the second paragraph of section 112. Applicants respectfully request that the rejection of claim 21, 51-53 and 57-60 under 35 U.S.C. § 112, second paragraph, be withdrawn.

***Conclusion***

Upon entry of this amendment, claims 15, 21, 28–30, 51–54, and 57-60 will be in condition for allowance. Applicants respectfully request that the amendment be entered and that the claims be allowed at this time. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned attorney at 610.640.7855 to clarify any unresolved issues raised by this response.

As indicated on the transmittal accompanying this response, the Commissioner is hereby authorized to charge any debit or credit any overpayment to Deposit Account No. 50-0436.

Respectfully submitted,

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